8-425-10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expresswa
Dallas, Texas 75204-3145

August 19, 2003

Ref: 2003-DAL-WL-16

WARNING LETTER

Certified Mail
Return Receipt Requested

Elton Ray Davis, DVM, Owner
Canton Veterinary Clinic
1010 West Dallas
Canton, Texas 75103

Dear Dr. Davis:

Investigators from the US Food and Drug Administration (FDA) conducted an inspection at your veterinary practice on May 12 and 13, 2003. The investigation confirmed that you dispensed Sterile Penicillin G Procaine in an extra-label manner for two downer cows owned by [redacted] and that Dr. Timothy E. Eberhart, DVM, employed by you, dispensed Sterile Penicillin G Procaine in an extra-label manner for a sick cow owned by [redacted]

Extralabel use of approved animal drugs is permitted under section 512(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA) if the drug is used (i) by or on the order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship; and (ii) in compliance with regulations at 21 CFR Part 530. Because you did not dispense such drugs in conformance with 21 CFR Part 530, the drugs you dispensed were unsafe under section 512(a) of the Act and adulterated under section 501(a)(5).

Our investigation revealed that on December 9, 2002, you dispensed a 250 ml bottle of Sterile Penicillin G Procaine for two downer cows owned by [redacted] The penicillin was labeled with a Canton Veterinary Clinic label that prescribed a dosage of 30 ml twice a day for seven days. Your label did not indicate a pre-slaughter withdrawal time as required by 21 CFR 530.12(e). On or about December 10, 2002, [redacted] offered this animal to a dealer/hauler who delivered the animal for slaughter as human food on December 11, 2002 at [redacted] The cow was found by USDA to bear illegal tissue residues of penicillin at 0.16 ppm in

kidney and 0.09 ppm in muscle. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21 CFR 556.510). The presence of this drug, at the reported levels, in edible tissue of this animal, causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

The investigation also revealed that on December 16, 2002, Dr. Timothy E. Eberhart, DVM, a staff veterinarian employed by you, dispensed a 250 ml bottle of Sterile Penicillin G Procaine for a sick cow owned by [redacted] The penicillin was labeled with a Canton Veterinary Clinic label that prescribed a dosage of 30 ml twice a day for seven days. Your label did not indicate a pre-slaughter withdrawal time as required by 21 CFR 530.12(e). On or about December 18, 2002, [redacted] consigned this animal to a dealer/hauler who delivered the animal for slaughter as human food on December 19, 2002 at [redacted] The cow was found by USDA to bear illegal tissue residues of penicillin at 0.17 ppm in kidney, 0.24 ppm in liver, and 0.49 ppm in muscle. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21 CFR 556.510). The presence of this drug, at the reported levels, in edible tissue of this animal, causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Your prescribing of penicillin in these circumstances resulted in the following deviations from 21 CFR Part 530:

- The label did not include a specified withdrawal time for meat which might be derived from the treated animals. The drug Penicillin G Procaine labeled use by the manufacturer in cattle, is 3,000 units per pound of body weight or 1 ml for each 100 pounds of body weight once a day, not to exceed 4 days, with a warning to withdraw the drug 10 days before slaughter in cattle.

- The extra-label use of the drug you prescribed resulted in a residue that is above an established tolerance or which may present a risk to the public health in violation of 21 CFR 530.11.

You failed to take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extra-label treatment in violation of 21 CFR 530.20(a)(2)(iv).

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to Reynaldo R. Rodriguez, Jr., Director, Compliance Branch, at the above letterhead address.

Sincerely yours,

Sylvia G. Yates

for Michael A. Chappell
Dallas District Director

MAC/SLK

cc: Dr. Timothy E. Eberhart, DVM
Canton Veterinary Clinic
1010 West Dallas
Canton, Texas 75103